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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,939	12/29/2000	Bruce L. Gibbins	01005-0121 (41946-251368)	9231
7590 12/28/2007 Mary Anthony Merchant Ph D Trouman Sanders LLP Bank of America Plaza 600 Peachtree Street NE Suite 5200 Atlanta, GA 30308-2216				
			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/752,939	<b>Applicant(s)</b> GIBBINS ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 8, 21-28, 31-35, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8, 21-28, 31-35, 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 10/11/2007.

Claims 3, 5, 7, 9-20, 29, 30, 36, and 37 have been canceled.

Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38-39 are pending.

1. Claim 39 as amended is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim does not require oxygen generated from the reaction of catalyst and reactant.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38 are included in the prosecution.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amendment recite: "catalyst dispersed in the matrix", "substantially where the catalyst is present" and "catalyst generating oxygen". These limitations have introduced new matter that has not been disclosed by the specification as originally filed. Nowhere in the specification have applicants disclosed that the catalyst is dispersed in the matrix, or that catalyst generates oxygen. On page 21 of the present specification, lines 10-15, applicants disclosed that: "The chemical reaction between the hydrogen peroxide (second reactant) and the carbonate catalyst (reactant) caused the formation of water and gaseous oxygen which in turn causes the formation of closed cells or bubbles within the matrix". On page 26 of the present specification, lines 24-29, applicants

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disclosed that: "A catalytic decomposition of hydrogen peroxide occurs resulting in the liberation of oxygen gas which becomes entrapped as bubbles formed in situ. The hydrogen peroxide is not part of the compounding of the matrix, but it is in the treatment after the formation of the matrix stock". Example 1, on page 43 of the present specification describes the preparation of oxygen containing closed cell foam device. Therefore, oxygen is generated from decomposition of hydrogen peroxide by the catalyst, and not generated from the catalyst. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Furthermore, the expression "reactant" is broad and encompasses myriad of reactant, and applicants did not disclose any second reactant other than hydrogen peroxide, and applicants are not in possession of all reactants, applicants are entitled only for hydrogen peroxides.

Additionally, claims 21 and 22 recite the following elements as active agents in the matrix: herbicides, indicator of change in the environment, sera, nucleic acid, nucleosides, nucleotides, amino acids, and noble gases. It is not described in the specification how such elements act as active agents in terms of treating compromised tissues including wound dressing. Noble gases are inert and it is not described how they will help the wound or compromised tissue.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 6, 8, 21-28, 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as claim 1 recites "oxygen in closed cells in the cross-linked matrix substantially where the catalyst is present". The sentence is ambiguous, and makes the claim confusing and omits the structural relationship between the elements of the claims.

In claim 21, the following active agents listed bridging lines 2 and 3 of the claim is repeated again bridging lines 5 and 6: "antifungal agents, anti-bacterial agents, anti-viral agents, anti-parasitic agents".

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a):

9. Claim 1, 2, 4, 6, 8, 21-28, 31-35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0042587 ('587) in view of US 5,792,090 ('090).

The present claim 1 is directed to a product comprises matrix of cross-linked polyacrylamide polymer containing oxygen.

US '587 teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam that can be produced chemically and contains gasses including oxygen (paragraph 0036).

However, US '587 does not teach the chemical reaction that produces the gas in the foam as claimed in claim 1. US '587 does not teach polyacrylamide polymer as claimed in claims 3 and 37.

US '090 teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises hydrogel or polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The hydrogel or

foam can be guar gum or polyacrylamide and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam that can be produced chemically as disclosed by US '587, and produce the foam by oxygen gas delivered by the reaction of hydrogen peroxide and catalyst and replace the polymer by polyacrylamide as disclosed by US '090, motivated by the teaching of US '090 that such polyacrylamide polymer foam containing oxygen are optimal for minimization of infection, with reasonable expectation of having polyacrylamide cross-linked closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin.

### ***Response to Arguments***

10. Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive.

Applicants argue that there is no suggestion to replace the polymer of US '587 with polyacrylamide, and replacement of the polymer of US '587 with polyacrylamide of the '090 would altered the entire teachings of US '587 and renders the matrix of US '587 unsatisfactory to its intended purpose. US '587 does not teach oxygen produced by the reaction of catalyst and second reactant. US '587 teaches foaming preceding the cross-linking step and matrix can not cross-linked when containing oxygen. Applicants further



argue that US '090 teaches occlusive covering and does not teach oxygen delivery. The declaration showed the improved properties of the present invention over US '587.

In response to these arguments, applicants' attention is drawn to the scope of the present claims that is directed to a product comprising cross-linked matrix containing oxygen in closed cells. US '587 teaches polymeric cross-linked foam reservoir comprising cross-linked polymer and closed cell containing oxygen that can be produced chemically. US '587 suggests chemical formation of gas in the closed cells. US '090 teaches method for chemical generation of oxygen using catalyst and peroxide that is suitable for wound dressings and also teaches polyacrylamide matrix containing the oxygen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace cross-linked polymer with polyacrylamide and generate oxygen into the wound dressing disclosed by US '587 using catalyst and peroxide as used by US '090 because US '090 teaches polyacrylamide matrix comprising oxygen reduced infection, with reasonable expectation of having cross-linked polyacrylamide matrix containing closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin. The invention as a whole is taught by the combination of US '587 and US '090. See KSR Supreme Court of the United State Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC, et al. No. 04-1350) where it states That "However, the issue is not whether a person skilled in the art had the motivation to combine electronic control with an adjustable pedal assembly, but whether

a person skilled in the art had the motivation to attach electronic control to the support bracket of pedal assembly". In this present case, an article comprising cross-linked polyacrylamide matrix and oxygen in closed cells as claimed would have been obvious to one skilled in the art at the time the invention was made because the prior art recognized cross-linked polymeric matrix containing oxygen in closed cell delivered chemically and also recognized the suitability of polyacrylamide and the oxygen generation from reaction of catalyst and peroxide in wound dressing.

Additionally, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is *prima facie* obvious to reverse the order of the prior art process steps, *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), selection of any order of mixing ingredients is *prima facie* obvious. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix.

Regarding US '090, the reference is relied upon for the solely teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide. The cross-linked polymer matrix is taught by US '587, but US '587 does not specifically teach polyacrylamide. Further, US '090 teaches advantage of dressing comprising polyacrylamide polymer and oxygen generated from the reaction of catalyst and peroxide to supply oxygen to the wound for optimal healing and minimization of infection, and this would have been motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by US '587 with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as disclosed by US '090. The present language of the claims does not exclude the presence of occlusive layer, and US '090 teaches delivery of oxygen and does not teach that the occlusive layer to prevent the oxygen delivery, but to prevent escape of oxygen from the device to the atmosphere.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Regarding the declaration filed April 2007, it is argued that the present claims are directed to product comprising cross-linked polymeric matrix containing oxygen in closed cells, and the declaration is directed to wound dressing made of cross-linked polymeric matrix comprising closed cells containing oxygen. The scope of the claims is broad covering any article comprising cross-linked polymeric matrix containing closed cell containing oxygen while the declaration is limited to one specific embodiment of AcryMed wound dressing. The single and specific species of wound dressing of the declaration does not support the generic concept of the claims. Furthermore, applicants' declaration shows superior results, but expected from the combination of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali  
Primary Examiner  
Art Unit 1615

IG

A handwritten signature in black ink, appearing to read "Isis Ghali", written in a cursive style.

ISIS GHALI  
PRIMARY EXAMINER